K130696

i-SENS, Inc.
27-36 Gwangun-ro, Nowon-gu, Seoul 139-845, Korea Tel. 82-2-916-6191

510(k) Summary

(As required by 21 CFR 807.92)

Introduction:	**According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.**
Type of 510(k):	**Traditional 510(k)**
Submitter Information:	i-SENS, Inc. 27-36 Gwangun-ro, Nowon-gu, Seoul 139-845, Korea Tel.) +82-33-903-0767 Fax) +82-33-748-6191 e-mail: cylim@i-sens.com Contact Person: Chae Yun Lim AUG 2 1 2013
Prepared Date:	March 13, 2013
Device Name and Classification	Trade names: **CareSens N LINK Blood Glucose Monitoring System** **CareSens N LINK Multi Blood Glucose Monitoring System** Common name: Blood Glucose Test System Classification product code: NBW, CGA Regulation number: 21 CFR 862.1345 Glucose Test System Classification panel: 75, Chemistry Device class: Class II
Predicate Device	CareSens N Blood Glucose Monitoring System (k083468)
Device Description	The CareSens N LINK Blood Glucose Monitoring System (BGMS) consists of a blood glucose meter, single use test strips, and control solutions with two different glucose concentrations ("Control A" and "Control B" ranges, sold separately). The CareSens N LINK Multi BGMS consists of a blood glucose meter, multi use test strips and the control solutions("Control A" and "Control B" ranges). The CareSens N LINK and CareSens N LINK Multi BGMS are based on an electrochemical biosensor technology (electrochemical). The Systems measure the glucose level in whole blood samples using a small electrical current generated in the test strips.

Intended Use:	**CareSens N LINK Blood Glucose Monitoring System** The CareSens N LINK Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The CareSens N LINK Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro*) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes. The CareSens N Single Blood Glucose Test Strips are for use with the CareSens N LINK Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.
	CareSens N LINK Multi Blood Glucose Monitoring System The CareSens N LINK Multi Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The system is intended for use outside the body (*in vitro*) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with auto-disabling, single use lancing device. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes. The CareSens N Multi Blood Glucose Test Strips are for use with the CareSens N LINK Multi Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.
Comparison to the Predicate Device	The candidate devices have the following features that are identical to the predicate device: ■ Intended use ■ Measurement principle ■ Fundamental scientific technology ■ Operating ranges

	The candidate devices are different from the predicate device for the following aspects: ■ **The shape of meter's housing** ■ **Test result average range** ■ **Memory capacity** ■ **Battery type** ■ **Test strip ejector** The candidate devices and predicate device use same control solutions.
Type of Test	Quantitative, Amperometric method, Glucose oxidase *(Aspergillus sp.)*
Test Principle	The reagent on the test strip produces a small electrical current using glucose as a substrate in the blood sample. The meter converts electrical current to glucose concentration.
Summary of Pre-cleaning and Disinfection	The device is intended for single patient home use and multiple patients use in a professional healthcare setting. Disinfection studies were performed on the meter and lancing device by an outside commercial testing service to evaluate effectiveness of disinfectant, CLOROX GERMICIDAL Wipes (EPA Reg. No: 67619-12), in preventing the spread of blood-borne pathogens, using hepatitis B virus (HBV). The results demonstrated complete inactivation of live virus inoculated on the materials of the meter and lancing device. We have also demonstrated that 10,950 each of pre-cleaning and disinfection cycles for meter with the same disinfectant designed to simulate 3 years of multiple-patient use or 5 years (260 each of pre-cleaning and disinfection cycles for meter and lancing device) of single patient device use has no effect on the performance or the external materials of the meter and lancing device (for single patient use only).
Data demonstrating substantial equivalence	The candidate device was tested in accordance with ISO 15197:2003(E). Analytical performance testing included system accuracy, repeatability, and intermediate precision testing. A user performance evaluation assessed accuracy of results and usability of the device in the hands of intended users. The candidate device performed similarly to both the predicate device as well as to a laboratory reference method, the Yellow Springs Instrument (YSI). All testing demonstrated safety and effectiveness of the candidate device and substantial equivalence to the predicate device.

	Although unlike the predicate device, the candidate device provides for the wireless uploading of data from the monitor via Bluetooth transmission to a Bluetooth paired digital devices such as the PC. However, the wireless transfer of data has been validated and demonstrates a 100% correlation to actual monitor data. Therefore, there are no substantive differences between the products defined in this 510(k) submission and the predicate device.
Conclusion	**Based on the submitted information in this premarket notification, the candidate devices are substantially equivalent to the predicate device. Further, the candidate devices have met the performance, safety, and effectiveness of the device for its intended use.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2013

i-SENS, Inc
C/O Chae Yun Lim
27-36 Gwangun-ro, Nowon-gu,
Seoul 139-845, Korea

Re: K130696
Trade/Device Name: CareSens N Link Blood Glucose Monitoring System
CareSens N Link Multi Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: July 10, 2013
Received: July 11, 2013

Dear Chae Yun Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k130696

Device Name: CareSens N LINK Blood Glucose Monitoring System

Indications for Use:

The CareSens N LINK Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The system is intended for self-testing outside the body (in vitro) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.
The CareSens N Single Blood Glucose Test Strips are for use with the CareSens N LINK Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k1320696

Indications for Use Form

510(k) Number (if known): k130696

Device Name: CareSens N LINK Multi Blood Glucose Monitoring System

Indications for Use:

The CareSens N LINK Multi Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The system is intended for use outside the body (*in vitro*) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with auto-disabling, single use lancing device. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.
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Prescription Use _____ AND/OR Over-The-Counter Use X
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